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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Serial No:	09/118,730
Filed:	July 17, 1998
Inventors:	Ellington M. Beavers et al
Title:	METHOD OF MAKING FREE ACIDS FROM POLYSACCHARIDE SALTS
Examiner:	E. White
Art Unit:	1623
File No.:	281-28

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: COMMISSIONER OF PATENTS AND TRADEMARKS, WASHINGTON, D.C. 20231, ON THE DATE INDICATED BELOW.

BY William H. Eilberg

DATE 9/30/00

REPLY BRIEF FOR APPELLANTS

Appellants submit this Reply Brief in response to the Examiner's Answer mailed August 2, 2000.

This brief will respond specifically to the arguments, including new arguments, made in the Examiner's Answer, primarily those appearing on pages 4 and 5.

1. The Newly-Cited Merck Index Extract Is Not a Disclosure of Free Hyaluronic Acid

The Examiner cites the Merck Index to support his contention that free hyaluronic acid is known. This reference had not been previously cited in the present application.

The cited extract does not support the Examiner's position; on the contrary, it supports that of Appellants. The cited extract states that "hyaluronic acid" is found in the umbilical cord, in vitreous humor, and in synovial fluid. It is well-known in the art, that the umbilical cord, vitreous humor, and synovial fluid contain hyaluronic acid only in the form of its sodium salt, namely sodium hyaluronate.

Thus, it follows that the cited reference uses the term "hyaluronic acid" to refer to sodium hyaluronate. In doing so, the reference

perpetuates the common practice of referring to the sodium salt by using the name of the free acid. This imprecise terminology has appeared widely in the literature, as described in Appellants' main brief, and the Merck Index is no different from the other references in this regard.

If the Board has any doubts about the accuracy of the underlined sentence above, Appellants offer to submit a further Declaration, giving the pertinent factual details.

Appellants note also that, near the end of the cited extract from the Merck Index, various product names appear. All of these products are sodium hyaluronate, not free hyaluronic acid, as indicated in the cited extract itself.

Thus, the Merck Index extract is no more a disclosure of free hyaluronic acid than any of the other references considered so far in this case.

2. The Disclosure of Schultz Is Enabling Only for Sodium Hyaluronate, Not for Free Hyaluronic Acid

The Examiner's Answer again cites Schultz for its unsupported statement that free hyaluronic acid could be used instead of the sodium salt. But, as explained in the main brief, Schultz admits that all of its data were obtained with sodium hyaluronate. Schultz gives no information about how to make, or where to obtain, the free acid. In view of Appellants' repeated and unsuccessful attempts to obtain the free acid, it is clear that the free acid form was never available to Schultz.

Thus, Schultz is not an enabling disclosure with respect to free hyaluronic acid.

The Examiner attempts to address Appellants' "medical grade" limitation by observing that Schultz treated mammals with "hyaluronic acid". But

again, Schultz treated mammals only with sodium hyaluronate. No treatments with the free acid were ever made. Thus, the Examiner's argument is fatally flawed.

3. The "Medical Grade" Limitation is Present in the Claims on Appeal

The Examiner, on page 5, first full paragraph, appears to claim, for the first time, that the limitation that the claimed product be of medical grade is not in the claims. The Examiner is wrong.

The claims on appeal contain the explicit limitation that the product is "suitable for placement permanently or temporarily in the body". This is what is meant by "medical grade". This limitation is an integral part of the claims.

In the same paragraph, the Examiner continues to argue that Appellants are asserting a patent based on the process for making the product. Appellants have never made this kind of argument. Appellants have shown, by specific evidence, that the claimed product is new, not because of the method of making it, but because the product did not exist before Appellants made their invention. The declarations previously submitted show that Appellants were unable to obtain the product anywhere, despite repeated and diligent efforts. This inability led to the making of the product which is the present claimed invention.

4. The Examiner Mischaracterizes Appellants' Declarations

The Examiner's Answer, on page 5, third full paragraph, characterizes Dr. Beavers' declarations as describing the "difficulty" in obtaining the free hyaluronic acid. Dr. Beavers did not find it "difficult" to locate this product; he found it impossible. This point is the essence of Appel-

lants' claim, insofar as the claimed product is not commercially available, and, to the knowledge of Appellants, has never been known before. If the matter were merely one of "difficulty", there would be no valid claim for patentability of the product.

5. The Examiner's Characterization of Sodium Hyaluronate and Hyaluronic Acid as "Similar" is Scientifically Unsupportable

The Examiner, on page 3, fourth paragraph, and also on page 5, last paragraph, makes a general statement about the allegedly similar properties of sodium hyaluronate and free hyaluronic acid. At best, the Examiner's argument is overstatement; it is not a scientifically rigorous conclusion.

It is not accurate to say that a salt and its free acid are equivalents or near equivalents, at least for purposes of their behaviors inside the body. For example, solutions of sodium chloride are infused intravenously into hospital patients every day. But if the corresponding free acid, namely hydrochloric acid, were injected into the blood stream, the pH of the blood would be disastrously altered, and death of the patient would be the probable result.

Similarly, sodium hyaluronate is not the same as free hyaluronic acid, and there is no reason to expect that the two substances would behave similarly when placed in the body.

More importantly, the disclosure of sodium hyaluronate is not a disclosure or suggestion of free hyaluronic acid. Persons skilled in the art have long had access to sodium hyaluronate, but simply having a quantity of sodium hyaluronate does not enable one to make the claimed medical grade free acid form.

For the reasons given above, and in Appellants' main brief, Appellants urge that the decision of the Examiner be reversed.

Appellants submit three copies of this Reply Brief.

Respectfully submitted,

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